CHAMBERLAIN UNIVERSITY

Institutional Review Board (IRB) Handbook

THE CHAMBERLAIN IRB

Chamberlain University's Institutional Review Board (IRB) is accountable for ensuring that human subjects are protected during research/projects conducted by Chamberlain faculty, staff, or students.

The Chamberlain IRB's primary responsibility is to enforce the rules of the US Department of Health and Human Services and all relevant laws and regulations protecting the rights and welfare of human subjects recruited for or participating in research/projects.

The rules for IRBs evolved from landmark ethical standards, including the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report. The Chamberlain IRB is committed to ensuring that research at Chamberlain University meets the highest standards of ethical conduct as defined by these and other documents.

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THE ROLE OF THE INSTITUTIONAL REVIEW BOARD (IRB)

The Chamberlain IRB structure and function is derived from the Department of Health and Human Services (DHHS) Regulations, Title 45 of the Code of Federal Regulations part 46. These regulations (often referred to as "The Common Rule" because they are adopted by multiple federal departments and agencies) address minimum levels of human subjects' protection in research. In addition, the IRB closely follows policies and guidance provided by the Office for Human Research Protections (OHRP) in the United States Department of Health and Human Services, the federal agency charged with ensuring compliance with the regulations.

The IRB strives to create a supportive, collaborative environment for members of the Chamberlain community so that the design and implementation of research studies take place in a culture of ethical conduct. Nonetheless, the responsibility of the IRB is limited to the review of research/project proposals for compliance with ethical standards, federal rules, and other applicable laws.

The IRB does not provide primary advisement or mentoring on study design, nor does it assist students or faculty in creating required documents.

Specific areas of emphasis for the IRB include:

- Protecting the privacy of participants and the confidentiality of their data or records
- Respecting the autonomy and dignity of participants
- Ensuring that decisions concerning participation are voluntary
- Minimizing risks while maximizing benefits to participants
- Ensuring participants have adequate information to make informed decisions
- Ensuring that the benefits and risks of research are equally distributed among study participants
- Protecting vulnerable populations

Chamberlain's IRB applies the policies and guidance in this handbook to research that involves any of the following:

- Is conducted by or at the direction of the administration of Chamberlain University
- Is conducted by any Chamberlain University colleague who is serving as principal investigator or co-principal investigator of the study
- Involves Chamberlain University colleagues or the University itself in the collection of data about Chamberlain University students, employees, materials, products or programs
- Is conducted by any student enrolled at Chamberlain University
- Is conducted using any property or facility of Chamberlain University

REQUIRED HUMAN SUBJECTS PROTECTIONS TRAINING FOR ALL RESEARCHERS

The Chamberlain IRB requires that all persons submitting proposals to the IRB first complete human subjects research training provided by the Collaborative Institutional Training Initiative (CITI) at **citiprogram.org**. The courses provided by CITI present foundational information on the ethical and legal implications of human subjects research.

The CITI website will prompt you through registration. You will be asked to affiliate with an institution. Please select Chamberlain University. You may enroll in one of two training courses to fulfill this requirement: **Social & Behavioral Research** or **Biomedical Research**. Select the course that best aligns with your research study. You should allow between five to eight hours to complete the course. With your Chamberlain affiliation, you will not be charged for completing the course.

After finishing the CITI training, request a completion certificate which will serve as verification of successful completion. This certificate must be included with the study materials submitted to the IRB for review. You may also, at your own expense, obtain continuing education credits for completing the course. The CITI website will guide you through this process.

NOTE: Some research/projects involve specialized populations or include unique elements. The IRB may require the completion of additional modules if appropriate.

FREQUENTLY ASKED QUESTIONS (FAQs)

WHAT IS RESEARCH?

The Department of Health and Human Services (DHHS) defines research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." DHHS further defines a "human subject" as "a living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction with the individual and uses, studies or analyzes the information or biospecimens; or obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens" (45 CFR 46.102): DHHS does not define what constitutes generalizable knowledge or a contribution to generalizable knowledge, so IRBs must interpret the definition of research in light of dynamic scientific, academic, business and healthcare environments.

Newer forms of scholarly activity have become more important and commonplace in healthcare, including quality improvement (QI) and evidence-based practice (EBP) change activities. Using various methods, QI activities apply existing knowledge to improve existing system practices and processes at the local level; whereas EBP change activities in healthcare translate existing evidence, clinical expertise and patient values into clinical decision-making and practice. The setting-specific emphasis of QI and EBP change activities typically does not generate generalizable knowledge and, therefore, would not be considered human subjects research.

When dissemination of QI and EBP change projects' findings goes beyond the project setting, some have assumed that the findings become a contribution to generalizable knowledge. DHHS has further clarified that such dissemination does not, in and of itself, make QI "research". Presentation or publication of findings from non-research activities serve non-generalizable purposes, including strengthening the evidence base for a particular intervention or sharing process and implementation information in order to support future QI, EBP change and research projects.

The Chamberlain IRB defines generalizable knowledge as information that would be applicable to populations outside the study population in order to draw conclusions, expand theory or the knowledge base of a particular field of study or inform policy beyond the study setting. Projects that do not involve human subjects nor develop or contribute to generalizable knowledge do not need IRB review.

The Chamberlain IRB, however, will consider a project as research if:

- The aim of the project is to test a theoretical model or assess its applicability to a specific setting
- The project implements an intervention that is untested or deviates substantively from the evidence base
- The aim of the project is to replicate or extend a previous research study

The following proposals are provided as examples.

Example 1:
A student wants to implement and evaluate a program of follow-up telephone calls to clients of a wound care clinic in order to catch possible wound infections earlier in the treatment course. This program has been used effectively in other ambulatory clinics.

Not research, application of existing evidence. No IRB review required.

Example 2:
A student wants to implement and evaluate the introduction of group appointments for Hmong immigrants in a busy diabetes clinic. The literature suggests that group appointments are beneficial for Hispanic and White clients.

Research, intervention untested in this unique population. IRB review required.

Example 3:
An instructor plans to explore whether or not self-efficacy is influenced by level of acculturation in Haitian students.

Research, theory testing/expansion. IRB review required.

Example 4:
Congruent with the "flipped classroom" model, an instructor intends to introduce lectures that students access from home accompanied by devoted in-class case studies in a section of NR-340 and monitors student outcomes.

Not research, application of current evidence in a limited setting. No IRB review required.

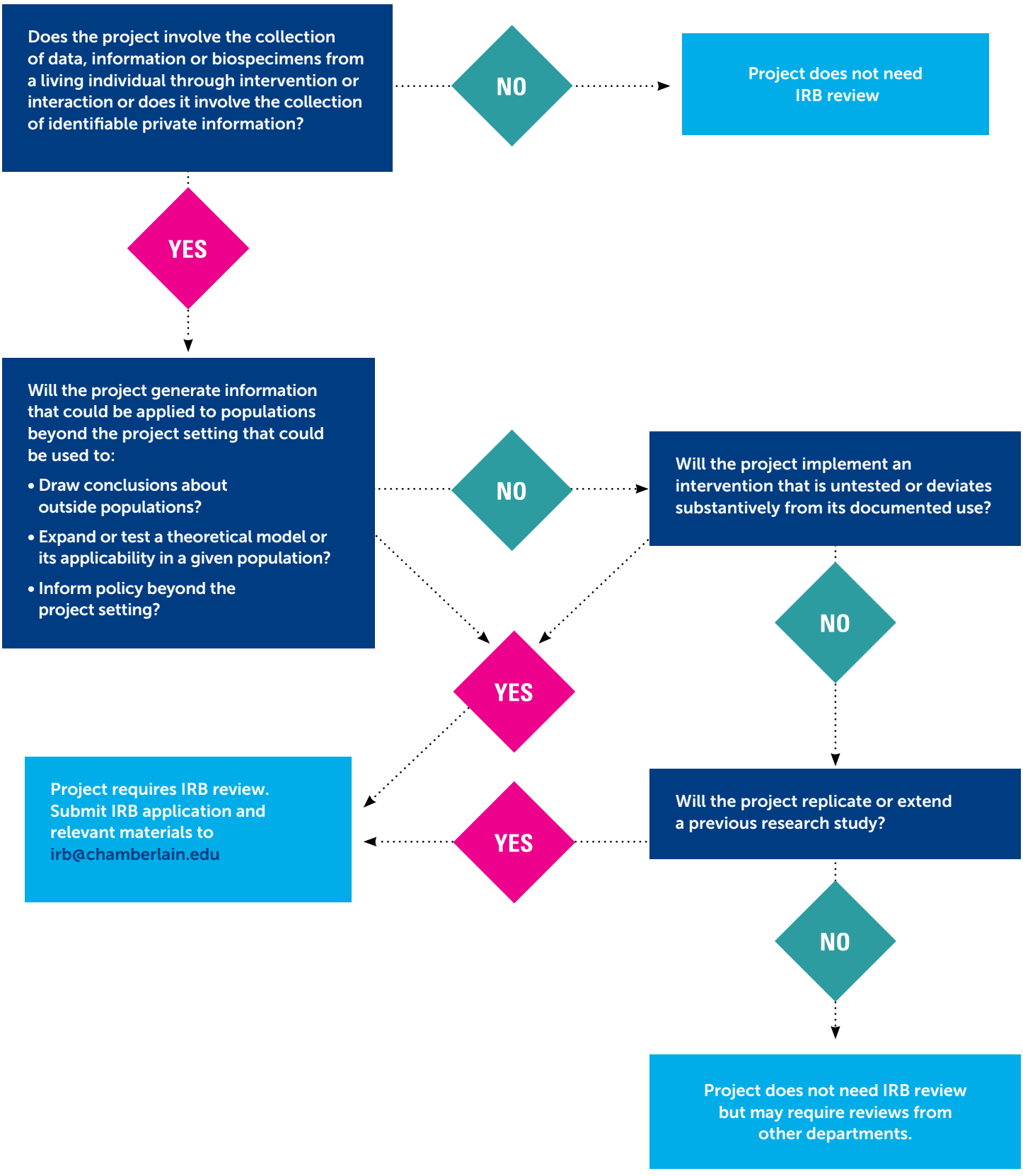
Example 5:
An instructor plans to integrate components from two, well-tested remediation models into one comprehensive model that will be piloted the next semester.

Research, substantive deviation from the evidence base. IRB review required.

If a project does not meet the criteria for research, the project is not required to undergo an IRB review. The project, however, may still be subject to reviews by other Chamberlain departments or teams. A decision tree to assist researchers in determining whether or not a project should be reviewed by the IRB is provided on the following page. If an investigator is not clear whether a specific project constitutes research, the researcher should contact the IRB at **irb@chamberlain.edu.**

Occasionally, a quality improvement or evidence-based practice change project may produce unexpected results that contributes to the knowledge base. In this case, the researchers may wish to change the aim of the project to that of a research study. At this point, the researchers should halt the project and seek IRB review and approval to continue. The IRB cannot retroactively approve a study.

DECISION TREE FOR DETERMINATION OF WHETHER A PROJECT REQUIRES REVIEW FROM CHAMBERLAIN UNIVERSITY'S INSTITUTIONAL REVIEW BOARD (IRB)



HOW DO I KNOW IF MY RESEARCH INVOLVES HUMAN SUBJECTS?

Federal rules and regulations provide the following definitions to help you determine if your project will involve human subjects.

Human subjects are defined as living individuals about whom a researcher will be obtaining information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or obtaining, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens.

Intervention is defined as physical procedures by which data or biospecimens are gathered (e.g., venipuncture, blood pressure, etc.) and/or manipulations of the subject or the subject's environment that are performed for research purposes. Interaction is defined as communication or interpersonal contact between the researcher and the subject (e.g., an interview).

Private information is defined as "information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Identifiable private information is "private" information for which the subject is or may readily be ascertained by the investigator or associated with the information. An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen" (45 CFR 46.102).

If your research project will include intervening or interacting with individuals or with their private identifiable information or identifiable biospecimens, then it involves human subjects.

Only proposals meeting both definitions of research and human subjects are required to be reviewed by Chamberlain's Institutional Review Board (IRB).

WHO WILL REVIEW MY RESEARCH?

Chamberlain's IRB has the authority to review and approve all human subjects research conducted within its jurisdiction. The members of the Chamberlain IRB must possess and maintain competency in the protection of human research subjects through past research and IRB experience and through ongoing professional development activities.

IRB members are appointed by the IRB administrator. Members include full-time faculty or staff with demonstrated experience and interest in the research process. In addition, the IRB must include at least one community member not affiliated with Chamberlain University and is not an immediate family member of an employee of Chamberlain University. Members must be capable of determining whether the proposed research complies with University commitments and regulations, applicable law, and standards of professional conduct and practice. Diversity in gender, background, race/ethnicity, and areas of scientific and ethics expertise must be present among the members. Occasionally, the IRB may use consultants if members lack specific areas of expertise relevant to a given proposal.

WHEN DO I SUBMIT MY RESEARCH PROPOSAL FOR REVIEW BY THE IRB?

Make sure you allow sufficient time for the IRB review when planning your research study. Research deemed to pose minimal or low risk of harm to human subjects is usually reviewed and approved in approximately two weeks. Studies involving greater risk or vulnerable populations, or are more complex in design and content may take as long as two-to-six weeks to review and approve. It is important to note, however, that delays might occur at any time, particularly if the submission is incomplete or unclear. These proposals require back-and-forth communication between the IRB and the submitter.

If your proposal is denied, you will have an opportunity to modify your planned research and resubmit your request. You should allow an additional four to six weeks for any resubmission and secondary review.

NOTE: The IRB may not approve studies that have already been completed. (retroactive approval). Under certain conditions, the IRB may review and approve studies that have already commenced; however, data collected from subjects prior to IRB approval may not be used if changes in current study protocols are required for IRB approval.

WHERE CAN I GET ASSISTANCE?

Preparing a research proposal and completing an IRB application for review can be challenging for inexperienced researchers. Students with questions about their proposals and IRB applications should work with their faculty advisors. Faculty and staff members with questions about their proposals and IRB applications should work with an experienced research mentor. Additional resources may be available through professional development materials available to Chamberlain colleagues.

WHAT ARE THE PROCEDURES FOR SUBMITTING AN APPLICATION TO THE IRB?

Researchers sometimes believe that developing a study proposal and the IRB application and materials is quick and easy. Additional preparation time is needed because you may be required to make revisions, seek additional input, consider new ideas, or grapple with difficult ethical issues. IRB forms contain a series of guided questions that require you to reflect on your study design, information about how your study will be conducted, and protection of human subjects and their private information and biospecimens.

In order to demonstrate that your plan for protecting human subjects is adequate, your completed forms must be intelligible to the reviewer (a person who may not have expertise in your specialty area) and convincing that the IRB's criteria for approval can be met. The reviewer will look for evidence that your decisions are based on thoughtful attention to responsible and ethical practices and a sufficient assessment of risk. The reviewer will determine whether you have adequate rationales for your recruitment strategies, informed consent processes, study procedures, and data management plans.

All forms and information needed for submission of a research proposal may be accessed on the IRB web page at **chamberlain.edu/about/leadership/institutional-review-board**. Completed forms should be submitted electronically as email attachments to **IRB@chamberlain.edu.** Make sure all forms are signed (where noted) by the appropriate parties prior to submission.

The amount of material that must be submitted to the IRB will vary on the type of study. All initial submissions require the following:

1. IRB Application Form for review
2. Confirmation of human subjects protection training as required by Chamberlain University
3. Documentation of prior proposal approval by the Chamberlain Office of Institutional Effectiveness, Accreditation, and Research (IEAR) for studies that will involve Chamberlain facilities, programs or services, or data obtained from Chamberlain students, faculty, or staff (For more information, contact IEAR at **cshane2@chamberlain.edu** or the Center for Faculty Excellence's faculty portal.)

When germane to the proposed study, other materials that must be submitted include:

1. Recruitment and advertisement materials
2. Study instruments (e.g., surveys, questionnaires, assessment tools, protocols, interview guides, etc.)*
3. A copy of the consent form that will be signed by participants
4. Copies of the information letters and directions given to participants
5. Copies of assent forms (for minors) and parental consent forms
6. Copies of approvals from other/collaborating IRBs
7. Letters of support
8. Other documents (e.g., HIPAA forms, authorizations, certifications, etc.)

NOTE: Failure to complete all IRB forms and/or failure to include all relevant materials will delay the approval process and may result in the submission being returned without being reviewed.

Study instruments such as surveys and questionnaires may not include the Chamberlain logo or other branding material without approval from Chamberlain Marketing.

WHAT DOES THE IRB CONSIDER IN ITS REVIEW?

The IRB looks closely at the materials submitted with the application to ensure that:

1. **Risks to subjects are minimized** (a) by using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk and (b) whenever appropriate, by using procedures already performed on the subjects for diagnostic or treatment purposes.
2. **Risks to subjects are reasonable in relation to anticipated benefits to subjects**, if any, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB considers only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB does not consider possible long-range effects of applying knowledge gained from the research (e.g., the possible effects of the research on public policy).
3. **Selection of subjects is equitable**. In making this assessment, the IRB considers the purposes of the research and the setting in which the research is conducted. The IRB is particularly sensitive to the special considerations of research involving vulnerable populations, such as children, prisoners, individuals with impaired decision-making capacity or economically or educationally disadvantaged persons.
4. **Informed consent** is sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by 45 CFR 46.116 Documentation of informed consent is expected unless otherwise waived.
5. The research plan makes **adequate provision** for the security of the data collected to ensure the safety of subjects.
6. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
7. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, students, direct reports of the researchers, or economically or educationally disadvantaged persons, **additional safeguards have been included** in the study to protect the rights and welfare of these subjects.

Chamberlain University's IRB has identified the following types of risk or discomfort as those which are most often considered during study review:

1. **Physical risks:** These risks include physical discomfort, pain, injury, illness, or disease brought about by the methods and procedures of the research.
2. **Psychological risks:** Psychological risks may be experienced during participation and/or after participating in the research. These risks include anxiety, stress, fear, confusion, embarrassment, depression, guilt, shock, loss of self-esteem and/or behavior considered atypical of the participant.
3. **Social/Economic risks:** Social risks include alterations in relationships with others that are to the disadvantage of the subject or to a group/community. These risks may involve embarrassment, loss of respect of others, labeling with negative consequences or diminishing opportunities and status in relation to others. Economic risks include study requirements that subjects pay for study procedures, may result in any loss of wages or income, and/or incur any risks to subjects' employability or insurability due to study participation.
4. **Legal risks:** Legal risks include the risk of criminal prosecution or civil lawsuit when research methods reveal that the subject has or will engage in conduct for which the subject or others may be criminally or civilly liable.

The following are particularly important areas carefully reviewed by the IRB.

RECRUITMENT OF SUBJECTS

All recruitment materials, including the final copy of printed advertisements, scripts, audio or video tapes, or websites, must be reviewed and approved by the IRB prior to use.

REQUIRED ELEMENTS OF RECRUITMENT MATERIALS

- **Study title.** Generally, the title of the study must be included in recruitment materials; however, there may be times when the study title may not be appropriate, including when deception or incomplete disclosure are part of the study design or if the wording of the title contains jargon that is unfamiliar to potential subjects. In the case of the latter, the purpose of the study may be provided in a manner that explicates the study title.
- **The word "research" or "study"**. It must be clear that the project is a research study.
- **Institutional affiliation**. Chamberlain University and/or the names of other institutions affiliated with the study must be included in materials.
- **Contact information.** A contact name and either phone number or e-mail address for the person(s) responsible for subject recruitment must be included in the materials.
- **Eligibility criteria.** Eligibility criteria, if applicable, must be briefly noted, especially if payment depends on meeting these criteria. For example, "English speaking only," "Women only," etc.
- **Compensation.** If applicable, a statement that participants will be compensated for their time and effort must be included. Acceptable language includes:
  - "You will be paid for your participation."
  - "You will receive a gift card to X for your participation."
  - "Participants will be compensated."
- **Amount of compensation.** The amount of payment must be included but should not be the most prominent element in the recruitment information. Payment should not be excessive, considering the nature of the project, so as not to be coercive or have undue influence. Payment should be stated as a range of amounts or "at least" or "up to" if payment is dependent on the level of participation.

RECOMMENDED ELEMENTS FOR RECRUITMENT MATERIALS

- The purpose of the project
- Brief statement of what is expected of subjects
- Time commitment asked of subjects
- Location where the study will take place
- Phrases such as "help needed" or "subjects wanted" should be avoided. The recommended wording is "You are invited" or "Participants invited."

ELEMENTS THAT ARE NOT ALLOWED ON RECRUITMENT MATERIALS

- The name of commercial sponsors or products
- Offers of compensation from the sponsor that would involve a coupon good for a discount on the purchase price of the product once it has been approved for market
- Promises of free treatment or services when the intent is only to say that subjects will not be charged for taking part in the study
- Use of terms such as "new treatment" or "new medication" without explaining that the item is investigational
- Claims that state or imply a certainty of a favorable outcome or other benefits beyond what is outlined in the consent document and protocol
- Use of exculpatory language such that it is stated or implied that prospective subjects will waive their legal, ethical and/or moral rights
- Use of bold or enlarged print or other means to emphasize payment or the amount to be paid

USE OF INCENTIVES TO RECRUIT SUBJECTS

The Federal government does not specifically regulate the use of incentives for research subjects but any incentive should not be of an amount or kind that might inhibit a potential subject's ability to choose freely whether or not to participate. Incentives cannot be coercive and must not pose undue influence on the subject in order to encourage participation. When reviewing a proposed incentive for appropriateness, the IRB considers subject characteristics, which incentives are being offered, and the conditions under which the incentive offer is made. Informed consent documents must include a detailed description of the terms of the incentive, including an account of the conditions under which a subject might not receive the full incentive. The use of incentives must comply with Chamberlain requirements.

COMPENSATION FOR PARTICIPATION

Compensation for participation in research cannot be used as coercive persuasion. Compensation, when offered, should recognize the investment of the subjects' time, risk, expense, and loss of wages or other inconveniences. When reviewing proposed compensation, the IRB will examine the informed consent documents for a detailed account of the terms of the compensation, including a description of any conditions under which a subject might not receive the full compensation offered. Compensation may not be withheld contingent on the subject's completion of the study. The use of compensation must comply with Chamberlain requirements.

INFORMED CONSENT

Informed consent is a communication process in which researchers share information about a study with potential subjects or their legal representatives so that they may make an informed and willful participation decision. This communication process may unfold in various ways, but the Office for Human Research Protections (DHHS) has specific requirements for informed consent as described in Federal regulations (45 CFR 46.116 and 45 CFR 46.117). These requirements are summarized below.

The Chamberlain IRB has the responsibility to determine whether proposed studies meet all these requirements and has the accountability to monitor studies, as needed, to ensure that researchers are maintaining adherence. to these requirements.

- Researchers must obtain legally effective informed consent from subjects or their legal representatives before they may participate in non-exempt studies approved by the IRB.
- Researchers must provide subjects or their legal representatives sufficient time to consider the study, ask questions and discuss concerns before agreeing to

participate. This must occur in an environment and context free from coercion and undue influence.

- Informed consent discussions and materials must be provided in a language and style that is understandable to subjects or their legal representatives.
- Researchers must provide subjects or their legal representatives all information a reasonable person would want to have to make an informed decision as to whether or not to participate in the study.
- Informed consent materials must begin with clear and concise information in order to understand the reasons why one would or would not choose to participate in the study. Materials must be formatted in a manner that facilitates comprehension.
- No informed consent may include exculpatory language in which the subject or legal representative is made to waive any legal rights or release the researcher, institution, or study agents from liability for negligence.
- Informed consent must include the following:
  - A statement that the study involves research
  - The purpose(s) of the study
  - The amount of time a subject is expected to provide by participating in the study
  - A description of what subjects are expected to do or provide in the study
  - Identification of any procedures that are experimental
  - A description of any foreseeable risks or discomforts to the subject
  - A description of any benefits the subject can reasonably expect by participating in the study
  - Disclosure of any alternative procedures or treatments that might be advantageous for the subject
  - A description of how the confidentiality of subject records will be maintained
  - An explanation of the compensation or medical treatment available and how these may be obtained for studies involving more than minimal risk
  - An explanation of whom to contact for questions about the study, questions about subjects' rights, and to report research-related injuries or problems. (The Chamberlain IRB also requires that consent materials include the IRB's email address, **IRB@chamberlain.edu**, as an additional contact.)
  - A statement that participation in the study is voluntary and that refusal to participate in or withdrawal from the study will not incur any penalty or loss of benefits to which the subject is otherwise entitled
- All studies that collect identifiable private information (information that one would expect to be private with which the researcher could readily ascertain the identity of the subject) or identifiable biospecimens must include one of the following statements in the consent materials:
  - A statement that identifiers might be removed from private information or biospecimens and that after such removal, information or biospecimens may be used for future research studies or distributed to other researchers for further studies without additional informed consent from subjects or their legal representatives; OR
  - A statement that information or biospecimens will not be used for future research, even if all identifiers are removed.

If applicable, the following information must also be provided to subjects or their legal representatives during informed consent:

- A statement that the planned treatment or procedure may involve risks that are unforeseeable
- A statement about the circumstances for which the subject's participation may be terminated by the researcher regardless of the informed consent provided
- Any additional costs to the subject for participating in the study
- The consequences of a subject's decision to withdraw from the study and procedures for an orderly termination of participation
- A statement that early study findings that might influence a subject's willingness to continue participation in the study will be provided to subjects or their legal representatives
- The approximate number of subjects participating in the study
- A statement that biospecimens, even if identifiers are removed, may be used for commercial profit and whether or not the subject will share in that profit
- A statement as to whether clinically relevant findings, including individual subject findings, will be shared with subjects and under what conditions
- A statement as to whether the research will or may involve whole genome sequencing of biospecimens

Informed consent must be documented by the use of a written informed consent form (including those in electronic format) approved by the IRB and signed by the subject or the subject's legal representative. A written copy must be given to the person signing the informed consent form. The IRB may grant a full or partial waiver to this requirement, if requested by the researchers, for studies that involve no more than minimal risk; could not be carried out practically by obtaining signed informed consent, and would not negatively affect subjects' rights and welfare if a waiver was granted.

The IRB may also grant a request to waive documentation of informed consent for these types of studies if it finds any of the following to apply to the study:

- The only document linking the subject to the study is the informed consent form, and a breach of confidentiality of the informed consent form serves as the principal study-related risk to subjects. (Each subject or legal representative must be asked whether subjects want the documentation that links the subject with the research. The subject's wishes will govern.)
- The study involves no more than minimal risk and involves no procedures that normally would require informed consent outside the research context
- The subject or subject's legal representative are members of a distinct cultural group where signing forms is not the norm, the study poses no more than minimal risk, and there is an alternative method for documenting that informed consent was obtained

If the IRB grants a waiver for the documentation of informed consent, the researcher must still provide subjects or their legal representatives with a written informed consent document in a language and format understandable to subjects or their legal representatives.

All consent forms and other informational documents provided to subjects must be clearly written, concise, free of unnecessary jargon and written at a reading level and language appropriate to the participating population. **It is recommended that materials provided to the lay public be written at about an eighth-grade reading level.** The IRB application requires researchers to provide the calculated reading level of all subject-facing materials.

SECONDARY SUBJECTS

In situations where a study subject is asked to provide information about other individuals that could identify those individuals, the other individuals may be considered secondary subjects. For example, in a study using a questionnaire sent to a daughter that contains personal questions about her father and other family members, the Institutional Review Board (IRB) will consider whether the information collected about the secondary subjects is private. The collection of sensitive information about secondary subjects without their consent may involve a breach of their privacy. With studies that involve primary and secondary subjects, the IRB requires that all subjects are afforded full levels of protection.

PRIVACY & CONFIDENTIALITY

The IRB evaluates all proposed research to ensure that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of identifiable data, information, and biospecimens. Federal guidelines differentiate between privacy and confidentiality. It is important that everyone understand the differences between these concepts.

Privacy relates to access to people and people's control over what information (including their identities) is provided to researchers. **Confidentiality** relates to how data that have been collected are secured, managed, or shared. Privacy may be invaded; confidentiality may be breached.

In developing strategies for protecting subjects' privacy, consideration should be given to:

- Methods used to identify and contact potential participants
- Settings in which an individual is interacting with a researcher
- Whether it is appropriate to have all personnel present for research activities
- Methods used to obtain information about participants
- The nature of the requested information
- Information that is obtained about individuals other than the target participants and whether such individuals meet the DHHS definition of human subject (e.g., a subject providing information about a family member for a survey)
- Protocols access only the minimum amount of information necessary to complete the study

Survey research that uses identifying information is not anonymous if subjects can be identified at any point in the study, including the recruitment of subjects or payment by check. Substituting subject identities with codes or removing personal identifying information after data have been collected does not make the study anonymous research.

When developing strategies for protecting confidentiality, consideration should be given to:

- How the study protocol protects the confidentiality of data and biospecimens through the use of coding systems, locked cabinets, password-protected and secure databases, etc.
- Whether the consent process adequately and clearly describes the confidentiality risks
- Whether a long-range plan is developed for protecting the confidentiality of research data, information, or biospecimens, including a schedule for the destruction of identifiers associated with the data, information, or biospecimens Whether the consent process, including forms, discloses those parties who could potentially have access to the research data and under what circumstances data may be shared (e.g., university officials, government agencies, sponsors)

The maintenance of privacy and confidentiality helps protect subjects from a variety of potential harms, including psychological distress, loss of insurance, loss of employment, and damage to academic or social standing that could occur from an invasion of privacy or a breach of confidentiality.

VULNERABLE POPULATIONS

If the proposed research involves a population that may be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, students, direct reports of the researchers, or economically or educationally disadvantaged persons, additional safeguards should be included in the study to protect the rights and welfare of these subjects. Vulnerable populations should never be used simply because they are convenient to access. Vulnerable populations may be used only if the aims of the study focus on the needs and concerns of these populations or are included to provide equity in the risks and benefits of the specific study.

Colleges and universities provide a rich source of potential research subjects. A concern with student participation in research conducted at Chamberlain is that their agreement to participate may not be truly voluntary. For example, students may volunteer to participate out of a belief that doing so places them in good favor with faculty (e.g., participation results in receiving better grades, recommendations, employment, or the like) or that failure to participate negatively affects their relationship with the researcher or faculty group in general (i.e., by seeming uncooperative or not part of the scientific community). When recruiting students, researchers must be aware of the possibility that students may feel pressured to participate in research and should make every effort to make clear that participation in research is voluntary and that their participation decisions do not affect their academic standing or their relationships with researchers or faculty.

Confidentiality is another concern when using students as subjects. As with any research involving human subjects, the researcher must make every effort to protect the confidentiality of data related to sensitive topics such as mental health, sexual activity, breaches of academic integrity, or the use of illicit drugs or alcohol. This is especially important for research involving students since other students may serve as members of the research team and may be involved in data collection and/or analysis. Researchers should ensure that everyone involved in the study understands the importance of protecting confidentiality.

PERSONS WITH IMPAIRED DECISION-MAKING CAPACITY

Individuals with psychiatric, cognitive, or developmental disorders, those who are active substance abusers, or those with limited English proficiency may be compromised in their capacity to fully understand the purpose, risks, and benefits of a proposed study. Researchers must provide a rationale for involving these subjects in a study and must include additional means to protect their rights and welfare.

Some individuals with psychiatric, cognitive or developmental disorders, or those who are active substance abusers may be institutionalized, which may further inhibit their ability to exercise free choice. It is also important to protect the privacy of all subjects and the confidentiality of information gathered in research exploring emotionally sensitive topics, since some individuals would not want their institutionalization to be revealed to others.

NOTE: All adults, regardless of their diagnosis or condition, should be presumed competent to provide informed consent unless there is evidence of a serious condition that would impair their reasoning or judgment. Individuals who have a diagnosed mental disorder may be capable of providing informed consent. Mental disability alone should not disqualify a person from consenting to participate in research. Someone who has been determined to be incompetent by a judge will have a court-appointed guardian who must be consulted and provide consent before that individual can be enrolled in research.

CHILDREN

Federal regulations provide additional protections for children involved in research. The IRB may approve research involving children as subjects by reviewing how the research aligns with four specific categories. These categories are based on the level of risk and the possibility of direct benefit to individual subjects and serve as the primary lens for review.

Consent from the child's parent or guardian must be provided unless the child has reached the age of consent for the procedure. The age of consent is determined by state law. When appropriate, assent from the child should be obtained. Federal code defines assent as a child's affirmative agreement to participate in research. A child's passive resignation to submit to a research procedure should not be interpreted as assent. Assent should be tailored to the comprehension level of the child. An assent form is optional and may be used for older children who can read and understand information about the study.

Discussion of applicable state law must be provided on the review application form if a study will involve children. Students must work with their faculty advisor to avoid violation of federal and state restrictions on research involving children when designing a research proposal.

PRISONERS

Federal regulations provide specific protections for prisoners involved in research. These requirements are based on the level of risk and the possibility of direct benefit to individual subjects. Documentation must be provided of how specific protections will be applied for any study involving prisoners. Students must work with their faculty advisor to avoid violation of federal and state restrictions on research involving prisoners when designing a research proposal.

WHAT HAPPENS AFTER I SUBMIT TO THE IRB?

Each application submitted to the IRB is briefly reviewed by the IRB administrator within five business days of receipt. You will receive an email with one of the following messages:

1. Your IRB submission packet has been received and is complete
2. Your IRB submission packet has been returned because it is missing the following documents: (a list of items that are missing will be included in the message)

The IRB administrator will determine the review pathway for each proposal submitted. By default, proposals are reviewed by all IRB members (full board review). Federal guidelines, however, provide options for alternative review pathways if a proposed study involves less than minimal risk to subjects and other criteria are met. These alternative pathways (e.g., expedited, limited, or exempt reviews) may require fewer reviewers and less review time.

Once your full submission packet has been reviewed by the IRB you will receive an email message within two to four weeks of proposal receipt with the IRB's decision, depending on the review pathway used. If changes are required or requested, an email detailing these changes will be sent. If the research is approved, the IRB will send the researchers an email identifying the review pathway used and the terms of the approval.

CONDITIONS OF APPROVAL

- Approval of a proposal by the IRB applies only to the procedures described in the submission or its subsequent revisions.
- Approval is not granted until all conditions or contingencies required by the IRB have been satisfied.
- Approval for any given proposal is valid only until the expiration date (usually one year) for studies that underwent a review by the full IRB committee. The IRB may require an approval period of less than one year, depending on various factors, including the level and type of risk involved in the research. Studies that were reviewed using an expedited or exempt process are not subject to additional reviews unless changes to the study occur, which require submission of a study amendment form. All studies must be conducted ethically and congruent with Federal guidelines.
- Investigators must immediately report to the IRB occurrences of promptly reportable non-compliance and any unanticipated problems involving risk or harm to subjects that arise in connection to the research (See below)

What if I need to make changes to my study after it's been approved?

All changes that deviate from the original submission or approved revisions must be approved by the IRB prior to implementation, except when necessary to eliminate immediate hazards to the subjects. Researchers must submit a Study Amendment Application form to the IRB. This form is available on the IRB web page located at **chamberlain.edu/about/ leadership/institutional-review-board.**

Changes reviewed via the exempt pathway do not require IRB review and approval unless those changes increase the level of risk to study subjects or change the procedures such that the study no longer meets the exception criteria outlined in the original approval letter sent by the IRB.

What must I do when the study is completed?

For all studies reviewed via an expedited or full board review pathway, researchers must submit to the IRB a completed Study Closure form when researchers are no longer interacting with human subjects or collecting private information, biospecimens and/or data from human subjects. Study Closure forms are available from the IRB web page at **chamberlain.edu/about/ leadership/institutional-review-board.**

What if my study goes beyond the approval period?

IRB approvals are valid for up to one year for studies that underwent full IRB review, unless otherwise stated by the IRB. If researchers believe their studies will remain active beyond the expiration of the IRB approval, researchers must submit a Continuing Review of Study Application form at least four weeks prior to the expiration date of the approval. Forms are available from the IRB web page at **chamberlain.edu/about/ leadership/institutional-review-board**. Studies that underwent expedited or exempt review are not required to undergo a continuing review process.

OTHER CONSIDERATIONS

QUALITY OF MATERIALS SUBMITTED TO THE IRB

Materials submitted to the IRB are professional documents. They should reflect the researcher's best professional writing, preparation, and attention to detail. Materials may be reviewed by auditors from government agencies or grant sponsors; therefore, submitted materials cannot be considered as internal documents. Researchers should consider their materials in a similar manner as grant applications, manuscripts, and professional presentations.

The IRB will not deny approval based solely on the quality of the materials. The IRB, however, may request that the researcher make revisions, particularly if poorly written materials lack clarity and transparency or if materials that will be provided to external audiences lack professionalism.

UNANTICIPATED PROBLEMS & ADVERSE EVENTS

An **unanticipated problem**, as defined by the Office of Human Research Protections, DHHS is an event, experience, or outcome that meets the following:

- Is unexpected in terms of nature, severity, or frequency based on the IRB-approved study protocol and the subject population being studied
- And is related or possibly related to participation in the research study
- And suggests that subjects or others are at a greater risk of harm (including physical, psychological, economic or social) than was previously known or recognized.

Unanticipated problems often require notable changes to a study's protocol and/or informed consent processes.

An **adverse event** is defined as an unfavorable medical occurrence (psychological or physical harm), including a sign, symptom, or disease temporarily associated with participation in the research, whether or not it might be related to a subject's participation in the research study. If an adverse event meets the three criteria that define an unanticipated problem, the adverse event is also considered an unanticipated problem.

Researchers must notify the IRB of any unanticipated problem or adverse event within 72 hours of becoming aware of the problem or event by submitting an Unanticipated Problem/Adverse event form available from the IRB web page at **chamberlain.edu/about/leadership/institutional- review-board**. The IRB will explore the nature of the problem or event and respond as required by regulations and policies.

PROPOSALS THAT ARE ONLY CLASS ASSIGNMENTS

Some Chamberlain courses may require students to complete research proposals..The Chamberlain IRB does not review student proposals completed in academic courses if the purpose of these proposals is only to enhance learning about the research process and no data will be collected. Instructors assigning activities involving data collection with human subjects are obligated to determine whether the data collection meets the definition of reviewable research.

A proposal initially developed to learn about research methods may be used for future research only if the student submits a full IRB packet and receives approval.

MONITORING OF IRB-APPROVED STUDIES

Various funding agencies and sponsors of studies require IRBs to monitor study progress, compliance with approved protocols and materials, as well as measures to ensure subject safety and data security. Monitoring procedures vary depending upon the requirements of the funding agency or sponsor and may include submission of documents, data, or other information to the IRB for review and/or on-site monitoring of study procedures. The IRB will collaborate with all stakeholders in developing and implementing a study monitoring plan.

Further, as a condition of study approval, the IRB retains the right to monitor any study it deems necessary, whether or not the study involves funding agencies or sponsors. Researchers are required to comply with all aspects of a study monitoring plan and requests made by the IRB.

NON-COMPLIANCE WITH IRB REQUIREMENTS

Researchers are required to notify the IRB within 72 hours of becoming aware of occurrences of promptly reportable non-compliance. Such occurrences include:

- Enrollment of subjects before IRB approval has occurred and/or after IRB approval has lapsed
- Continued treatment of subjects after IRB approval has lapsed without first obtaining permission from the IRB
- The principal investigator enrolls a subject into a study who does not meet all of the inclusion/exclusion criteria resulting in placing the subject at risk of harm
- Enrollment of children, prisoners, pregnant women, and fetuses without prior IRB approval
- Use of an unapproved consent form
- Changes in the study protocol without IRB approval except in cases of potential immediate harm to participants
- A breach of confidentiality
- Unresolved complaint from any study participant

The IRB administrator will investigate all occurrences of promptly reportable non-compliance. Further, investigations will be initiated if non-compliance with other federal law, state law or any restriction, limitation or other condition imposed on a research study is suspected or alleged. The researcher will be informed of any allegations and given time to respond. The IRB will submit a report of any occurrence of non-compliance to the University provost and the appropriate academic administrators and include recommendations for further actions. Recommendations may range from dismissal of the allegations up to revocation of IRB approval of the study. The IRB exercises the right to suspend an ongoing study at any time if it believes subjects are at undue risk of harm.

WORKING WITH MULTIPLE IRBS

It is not uncommon for multiple IRBs to have an interest in a single study. Typically, this occurs when a study occurs in multiple sites; but multiple IRBs can become involved if a researcher has an employer or sponsor affiliation that differs from the location(s) where the study occurs. In order to avoid multiple IRB reviews and potential conflicts in study oversight, researchers may choose to initiate a single-IRB arrangement. In such arrangements, one IRB (the reviewing IRB) assumes primary responsibility for the review and oversight of the study. Other IRBs (relying IRBs) cede primary responsibility to the reviewing IRB. All parties must agree to the conditions delineated in reliance agreements to formalize a single-IRB arrangement. Information about single-IRB arrangements and forms is available on the IRB web page at **chamberlain.edu/about/leadership/institutional-review-board.**

RETENTION OF STUDY RECORDS

In congruence with the University's records retention policy, all study records should be retained in a secure manner by the researcher for no less than seven (7) years from the date the study was approved by the IRB. Study records include but are not limited to all communication with the IRB; all IRB-approved forms such as applications, forms and materials; study protocol(s); recruitment materials; data collection tools and interview guides; signed informed consent forms; reliance agreements; and information materials provided to study participants. Researchers may be requested to provide these materials anytime within this seven-year time frame.

STUDENT RESEARCH POLICY

All persons, including students, engaged in human subjects research must adhere to the policies and procedures governing the conduct of human subjects research. Beyond the policies and procedures applicable to all researchers, students enrolled in a Chamberlain academic program and their faculty study advisor/supervisors must adhere to the following additional requirements:

- All Chamberlain students engaged in human subjects research as researchers or research assistants must complete human subjects protections training prior to initiating a research study. This training will be determined by the IRB and may or may not differ from the training required of non-student researchers. Specific content of the training may also differ depending upon the research topic and/or scope.
- Chamberlain students conducting research must have a designated faculty study advisor/ supervisor.
- The faculty study advisor/ supervisor must serve as a co-principal investigator for the proposed research study and must co-sign all study materials submitted to any Chamberlain review body. (NOTE: Serving in the role as a co-principal investigator is for research review and accountability purposes only. This role has no relevance to the potential authorship of a study's dissemination materials. How this role contributes to faculty's personal scholarship productivity is determined by the faculty's program and the University.)
- The faculty study advisor/ supervisor must be included in all communications and actions with the IRB.
- Non-faculty Chamberlain colleagues may serve as a study advisor/ supervisor for a student if approved by the student's academic program and the IRB.
- Chamberlain students engaged in human subjects research as researchers or assistants may not have access to subjects' personal identifying information nor an ability to re-identify research subjects if possible. If access is unavoidable (e.g., participating in interviews with research subjects), students may not engage with subjects or subjects' data from the student's academic location (e.g., campus) or academic program (for programs delivered online) unless an exception is granted by the IRB.
- For research conducted by Chamberlain students, students must identify themselves as student researchers in recruitment and informed consent materials, as well as provide the names and contact information of faculty study advisors/supervisors.
- Chamberlain colleagues who are conducting research as a requirement to an academic program to which they are enrolled must also have a faculty study advisor/supervisor. This faculty study advisor/supervisor must approve all materials submitted to the IRB and must be included in all communications the colleague has with the IRB.

IRB QUALITY IMPROVEMENT

The IRB strives to improve and maintain the quality of its processes and ensure the ethical conduct of research affiliated with Chamberlain. To accomplish this, the IRB employs various strategies to assess process quality and identify areas in need of improvement. One strategy includes the use of audits. The IRB routinely audits a percentage of reviewed studies to ensure that approved study protocols are followed. Researchers may be contacted by the IRB to provide information on study progress and compliance with study protocols. The audit may require the submission of study documents as allowable by law. Researchers are required to comply with IRB audits as a condition of approval of their studies. More information will be provided to researchers at the time of the audit.

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